UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to**: *Track Three Cases*	**MDL No. 2804** **Case No. 17-md-2804** **Judge Dan Aaron Polster**

DECLARATION OF STEVEN N. HERMAN IN SUPPORT OF THE PHARMACY DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DR. KATHERINE KEYES

EXHIBIT 9

E-FILE

SHORT FORM ORDER INDEX NO. 400000/2017

SUPREME COURT - STATE OF NEW YORK
NEW YORK STATE OPIOID LITIGATION PART 48 - SUFFOLK COUNTY

PRESENT:
HON. JERRY GARGUILO
SUPREME COURT JUSTICE

DECISION AFTER FRYE HEARINGS

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IN RE OPIOID LITIGATION

ALL PARTIES VIA NYSCEF
(FULL PARTICIPATION RECORDED)

In the course of presiding over this litigation [IN RE OPIOID LITIGATION], the Court referenced "the creation and continuation of what all parties uniformly describe as the "opioid crisis" (SFO motion seq. 116 January 28, 2020 NYSCEF Doc. No. 3382). No one denies that an "opioid crisis" exists. Whether it constitutes an actionable Public Nuisance will be determined at trial.

Prior hereto, this Court recited dosage averments alleged to be grossly excessive:

> Between 2006 and 2019 there were 29,008,434 shipments of opioid pills to customers in New York. (Expert Report of Lacey Keller at 15.) Stated differently, 7,900,367,355 dosage units and 206,200,688,744 Morphine Milligram Equivalence ("MME") (the measuring power of an opioid) were shipped to customers in New York. In Suffolk County, specifically, there were 2,747,528 shipments of opioids between 2006 and 2019, comprising 722,431,418 dosage units and 20,300,087,036 MMEs. Over this time period, Suffolk County was flooded with more shipments and dosage units (such as pills or patches) than any other county in New York. During the same period in Nassau County, there were 2,089,741 shipments of opioids, comprised of 579,879,700 dosage units totaling 20,394,155,889 MMEs. Nassau County received the higher total of MMEs—the measuring power of an opioid—than any other county in New York. What this means in human terms is that dispensers, including pharmacy chain defendants, received enough opioids for every resident in Nassau County to

> consume 36.4 dosage units or 965 MMEs every year from 2006 to 2014. In Suffolk County, this translates into enough opioids for every resident in the county to consume 42.4 dosage units or 1,097 MMEs every year from 2006 to 2014 (See Decision on motion sequence #158, NYSCEF Doc No. 7258).

This litigation, in major part, focuses on the issue of responsibility or in the context of law (proximate causation): Who is or is not legally accountable? *Frye* hearings conducted herein were focused primarily on causation issues.

The Court conducted *Frye* hearings taking direct testimony and cross examination of experts proffered by the Plaintiffs. Plaintiffs produced the following witnesses as proposed experts:

(1) Dr. David Kessler;
(2) Mr. James Rafalski;
(3) Dr. Craig McCann;
(4) Dr. Anna Lembke;
(5) Dr. Katherine Keyes; and
(6) Dr. James Tomarken.

The hearings spanned 7 days (August 14, 17, 18, 19, 2020 and September 9, 10 and 14, 2020). Subsequent thereto, the parties submitted post hearing submissions.

A New York court will permit expert testimony based on a novel scientific theory, principle or procedure only if such theory, principle or procedure has gained general acceptance in the relevant scientific field (*People v Wesley*, 83 NY2d 417, 422, 611 NYS2d 97 [1994]; *Matter of State of New York v Marcello A.*, 180 AD3d 786, 790, 118 NYS3d 688, 692 [2d Dept 2020]; *Matter of State of New York v Hilton C.*, 158 AD3d 707, 709, 70 NYS3d 565, 567 [2d Dept], appeal withdrawn 31 NY3d 1077, 79 NYS3d 98 [2018]; *see Frye v United States*, 293 F 1013 [DC Cir 1923]). A *Frye* hearing asks not whether the proposed novel scientific evidence is universally endorsed by the scientific community, but whether it has achieved general recognition for reliability "in the particular field in which it belongs" (*Frye v United States*, 293 F 1013, 1014; *see People v Wesley*, 83 NY2d 417, 611 NYS2d 97). "The process is meant to assess 'whether the accepted techniques, when properly performed, generate results accepted as reliable within the scientific community generally'" (*People v Brooks*, 31 NY3d 939, 941, 73 NYS3d 110, 112 [2018], *quoting People v Wesley*, 83 NY2d 417, 422, 611 NYS2d 97, 100), and has been used to

determine the admissibility of expert testimony on new social and behavioral theories (*see People v Wernick*, 89 NY2d 111, 651 NYS2d 392 [1996]; *People v Taylor*, 75 NY2d 277, 552 NYS2d 883 [1990]). "*Frye* is not concerned with the reliability of a certain expert's conclusions, but instead with whether the [expert's] deductions are based on principles that are sufficiently established to have gained general acceptance as reliable (*Lipschitz v Stein*, 65 AD3d 573, 576, 884 NYS2d 442, 445 [2d Dept 2009]). The burden of proving general acceptance within the scientific community rests upon the party offering the disputed expert testimony (*Ratner v McNeil-PPC, Inc.*, 91 AD3d 63, 70, 933 NYS2d 323, 329 [2d Dept 2011]; *Cumberbatch v Blanchette*, 35 AD3d 341, 342, 825 NYS2d 744, 745 [2d Dept 2006]). General acceptance of a novel scientific theory, principle or procedure can be demonstrated through scientific or legal writings, judicial opinions, or expert opinions other than those of the proffered expert (*Dovberg v Laubach*, 154 AD3d 810, 813, 63 NYS3d 417, 429 [2d Dept 2017]), as well as through texts, laboratory standards, and scholarly articles (*People v Wesley*, 83 NY3d 417, 437, 611 NY2d 97, 108). A *Frye* hearing generally is not warranted absent a novel or experimental scientific theory (*People v Brooks*, 31 NY3d 939, 941, 73 NYS3d 110, 112; *see Guerra v Ditta*, 185 AD3d 667, 127 NYS3d 148 [2d Dept 2020]; *Nonnon v City of New York*, 32 AD3d 91, 819 NYS2d 705 [1st Dept 2006], affd 9 NY3d 825, 842 NYS2d 756 [2007]), and the *Frye* rule does not apply where an expert's testimony is based on training or personal experience (*see People v Oddone*, 22 NY3d 369, 980 NYS2d 912 [2013]; *Doviak v Finkelstein & Partners*, LLP, 137 AD3d 843, 27 NYS3d 164 [2d Dept 2016]). (*emphasis added*)

Once the reliability concern regarding novel scientific evidence is satisfied, the *Frye* inquiry ends and the court's focus moves to whether a proper foundation was established for the admissibility of the expert evidence at trial (*see People v Williams*, 35 NY3d 24, 124 NYS3d 593 [2020]; *People v Brooks*, 31 NY3d 939, 73 NYS3d 110; *Parker v Mobil Oil Corp.*, 7 NY3d 434, 824 NYS2d 584 [2006]; *People v Wesley*, 83 NY2d 417, 611 NY2d 97). In determining whether a foundation exists for the proposed expert's testimony and opinion, the court considers the specific reliability of the theory, procedures, techniques or data actually employed by such expert (*see Cornell v 360 W. 51st St. Realty*, LLC, 22 NY3d 762, 986 NYS2d 389 [2014]; *Parker v Mobil Oil Corp.*, 7 NY3d 434, 824 NYS2d 584; *Cleghorne v City of New York*, 99 AD3d 443, 952 NYS2d 114 [1st Dept 2012]), as well as whether the expert possesses "the requisite skill, training, education, knowledge or experience from which it can be assumed the information imparted or the opinion rendered is reliable" (*Matott v Ward*, 48 NY2d 455, 459, 423 NYS2d 645, 647 [1979]; *see Doviak v v Finkelstein & Partners, LLP*, 137 AD3d 843, 27 NYS3d 164). A court may reject the admission of expert testimony when 'there is simply too great an analytical gap between the data and the opinion proffered" (*Cornell v 360 W. 51st St. Realty, LLC*, 22 NY3d 762,

780, 986 NYS2d 389, 402, *quoting General Elec. Co. v Joiner*, 522 US 136, 146, 118 S Ct 512, 519 [1997]). (*emphasis added*)

Finally, all are again reminded that even though a scientific theory, procedure or technique is accepted as reliable within the relevant scientific field that does not complete the court's inquiry, as it also must decide whether admission of expert testimony on a particular matter would assist the jury in reaching a verdict (*see People v Taylor*, 75 NY2d 277, 552 NYS2d 883). Expert testimony is proper "when it would help to clarify an issue calling for professional or technical knowledge, possessed by the expert and beyond the ken of the typical juror" (De Long v County of Erie, 60 NY2d 296, 307, 469 NYS2d 611, 617 [1983]; *see Matott v Ward*, 48 NY2d 455, 423 NYS2d 645). "As a general rule, an expert should be permitted to offer an opinion on an issue which involves professional or scientific knowledge or skill not within the range of ordinary training or intelligence" (*Selkowitz v County of Nassau*, 45 NY2d 97, 102, 408 NYS2d 10, 12 [1978]). Thus, expert testimony on causation may be excluded if the court finds that the jury, having an understanding of the relevant facts, can make such a determination using everyday knowledge and experience (*see People v Santi*, 3 NY3d 234, 785 NYS2d 405 [2004]; *Klein v Hyster Co.*, 255 AD2d 425, 680 NYS3d 583 [2d Dept 1998]).

The Court again referenced the Guide to New York Evidence. There are two rules covering the admissibility of opinion testimony. Rule 7.01 covers opinions of expert witnesses and basically covers the substance of CPLR § 4515 covering the form of expert opinion as well as the general substance of Federal Rules of Evidence (FRE) 702, 703, 704 and 705, along with New York, common law cases. Rule 7.01 codifies the *Frye Plus* test, that is "general acceptance" within the relevant scientific community and the "scientific reliability" standard of *Daubert, Joiner &Kumho Tire*.[1]

Rule 7.01 Opinion of Expert Witness provides as follows:

> (1) A person qualified as an expert by knowledge, skill, experience, training, or education, may testify to an opinion or information concerning scientific, technical, medical, or other specialized knowledge when:
>
> (a) the subject matter is beyond the knowledge or understanding, or will dispel misconceptions, of a typical finder of fact; and
> (b) the testimony will help the finder of fact to understand the evidence or

[1] *Frye v US*, 293 F. 1013 (App. D.C. 1923), *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997) and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999).

> determine a fact in issue, especially when the facts cannot be stated or described in such a manner as to enable the finder of fact to form an accurate judgment about the subject matter.

(2) Where the subject matter of the testimony is not based on the personal training or experience of the witness but rather is based on scientifically developed procedures, tests, or experiments, it must also be (or have been) established that: (a) there is general acceptance within the relevant scientific community of the validity of the theory or principle underlying the procedure, test, or experiment; (b) there is general acceptance within the relevant scientific community that the procedure, test, or experiment is reliable and produces accurate results; and (c) the particular procedure, test, or experiment was conducted in such a way as to yield an accurate result. (See, *Frye* "general acceptance" plus "scientific reliability" test and FRE 702 and *Daubert, Joiner and Kumho Tire*.)

(3) Testimony in the form of an opinion or inference that meets the foregoing criteria for admissibility is admissible even if it embraces an ultimate issue to be decided by the trier of fact. (See, FRE 704).

(4) An expert need not assert a conclusion with certainty, so long as the expert demonstrates a degree of confidence in the conclusion sufficient to satisfy accepted standards of reliability in the expert's field. (See, FRE 703 and 705).

Adherence to Rule 202.69 of the Civil Rules for Supreme and County Courts requires the Courts:

> (3) Coordination with Federal or other states' actions. If actions related to those pending before a Coordinating Justice are proceeding in Federal courts or in the courts of other states, the Coordinating Justice shall consult with the presiding judge(s) in an effort to advance the purposes of this section. Where appropriate, the Coordinating Justice, while respecting the rights of parties under the Civil Practice Law and Rules, may require that discovery in the cases coordinated pursuant to this section proceed jointly or in coordination with discovery in the Federal or other states' actions.

Pursuant to that direction, the Court has studied the decisions of Judge Dan Aaron Polster,

Federal District Court Judge currently presiding over the Multi District Litigation (MDL).

In essence, the jury is the last gatekeeper. At trial involving experts, the jury will be instructed as follows:

> You may reject any opinion if you find the facts to be different from the facts that formed the basis for the opinion. You may also reject an opinion if, after careful consideration of all the evidence in the case, including the cross-examination of the expert witness(es), you decide that an opinion is not convincing. In other words, you are not required to accept any opinion to the exclusion of the facts and circumstances disclosed by other evidence. Opinion testimony should be evaluated in the same way as the testimony of any other witness. It is given to assist you in reaching a proper conclusion; it is entitled to such weight as you find the witness's qualifications in the field warrant and must be considered by you, but is not controlling upon your judgment. New York Patter Jury Instruction 1:90 (General Instruction-Expert Witness):

"Cross-examination" is specifically mentioned in the instruction. As pertains to the hearings conducted, the Court on more than one occasion noted that the Defendants' rigorous cross examination of the proffered experts resembled an examination one would expect to hear at trial challenging both the foundation and the weight, if any, of an opinion.

Although some of the proffered experts testified as to methodology, its acceptance and the reliability of their findings, the Defendants chose to rigorously cross-examine those witnesses suggesting steps in their processes (missing steps) that should have been taken but were not. Defendants presented check lists (see Defendants "A"). Though those lists consisted of suggested steps in the process, the examiner elicited testimony that the witness did not consider those steps in arriving at an opinion. Although the cross-examination was rigorous, no witness was proffered by the Defendants to suggest either methodology, acceptance, or reliability of the results were flawed because of the missing steps (*see generally*, *People v Moore*, 194 A.D.2d 32).

The Court first heard from Dr. David Kessler, who served as Commissioner of the Food and Drug Administration from 1990 to 1997. He graduated from Harvard Medical

School and completed a residency in Pediatrics at Johns Hopkins University, and also has a law degree from the University of Chicago Law School. He was medical director of the Albert Einstein Medical Center for many years, and during that time taught food and drug law at Columbia Law School. Dr. Kessler worked for the United States Senate Labor and Human Resources Committee, where he concentrated on scientific issues including issues related to the FDA and the National Institutes of Health. He published a number of articles regarding FDA regulation of drugs and drug promotion in the 1980s and 1990s, and during that time developed significant expertise on the Federal Food Drug and Cosmetic Act (FDCA) and its regulations.

Dr. Kessler's testified of the responsibilities under the Food Drug and Cosmetic Act expected of the Defendants. Those standards appear to be founded in common sense with emphasis on public safety and protection. Dr. Kessler's baseline opinion is that the manufacturers marketing and promotion deviated from FDA standards, increasing the risk of abuse and endangering patient safety.

His report specifically names Jensen (Duragesic Nucynta); Endo (Percocet Opana ER, Opana ER reformulated); Teva (Actiq Fentora); Actavis (Kadian); and Mallinckrodt [2] (Exalgo Xartemis). He spoke of their support and involvement with pain advocacy, professional medical and trade group organizations resulting in expanding the use of opioids with concomitant risk of abuse. (APS/AAPM Guideline, American Academy of Pain Medicine, American Pain Foundation,[3] Federation of State Medical Boards). His report asserts contributions by certain manufacturers (Endo-$369,025, Teva-$130,000 and Mallinckrodt-$100,000).

The Court finds Dr. Kessler qualified and will allow him to offer opinion testimony consistent with his report and conditioned on proper foundations. (The opinions designated at 43-46 of his report play no role in the liability phase of these bifurcated proceedings).

Furthermore, Consistent with Judge Polster's ruling, Dr. Kessler may not offer conclusory legal opinions (tell the jury what the law is), (see In Re National Prescription Opiate Litigation Doc No. 2558).

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[2] The Court has been notified of a suggestion of bankruptcy on behalf of Mallinckrodt.

[3] The Pain Action Guide (Plaintiffs 16) American Pain Foundation Notes, Pain Medication rarely cause addiction. Morphine and similar pain medications, called opioids, can be highly effective for certain conditions. Unless you have a history of substance abuse, there is little risk of addiction when these medications are properly prescribed by a doctor and taken as directed. Physical dependence-which is not to be confused with addiction-occurs in the form of withdrawal symptoms if you stop taking these medications suddenly. This usually is not a problem if you go off your medications gradually.

Therefore, it is

ORDERED ADJUDGED AND DECREED that Dr. Kessler, subject to foundational requirements, separate and apart from the *Frye* analysis, may testify as an expert.

The Court next heard the testimony of Mr. James Rafalski,[4] former DEA Diversion Investigator. Mr. Rafalski received an undergraduate degree in public administration from Eastern Michigan University in 1999. In 2004, after 26 years as a law enforcement officer, Rafalski began work for the DEA as a Diversion Investigator in the Detroit Divisional Office, where he worked until June of 2017 as a Diversion Investigator. His duties consisted of conducting regulatory administrative, and criminal investigations. From 2011 to 2017, Rafalski was primarily responsible for conducting administrative, civil, and regulatory investigations of DEA registrants. In this capacity, he investigated the criminal conduct of individual physicians regarding improper opioid prescriptions and conducted regulatory investigations involving, *inter alia*, Distributors' compliance with DEA requirements regarding suspicious order monitoring systems("SOMS").

Certain facts are not in dispute:

1. All Defendants/Petitioners are subject to regulation by way of the Federal Controlled Substances Act and the New York State Controlled Substances Act.
2. Registrants are required to maintain effective controls to detect diversion.
3. Registrants through their constructed Suspicious Order Monitoring Systems (SOMS) are to flag orders that deviate substantially from the norm, and/or usual frequency.

As such, registrants are obliged to construct "effective" suspicious order monitoring systems. Rafalski's "expertise" rests on his work-life experience. Unlike any other witness, he does not hold advance degrees from high profile institutions, nor authorships in peer reviewed articles, etc…Does a *Frye* analysis preclude him, because his credentials are essentially experience (on the job training), from offering opinions? [5] He opines, that

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[4] Plaintiffs' Exhibit 1 and Defendants' Exhibits A-D (only marked for identification).

[5] It has gradually developed that lay witnesses may be permitted to testify beyond strictly factual observations where there is some indication that the witness is competent to have made a related valid conclusion. *See Hochberg v. Travelers Ins. Co.*, 270 A.D. 857 (2nd Dept 1946). The *Frye* rules do not apply where an expert's testimony is based on training or personal experience (*People v. Oddone*, 22 N.Y.3d 369).

certain Defendants both on a nationwide basis and specifically within New York State, Suffolk and Nassau Counties:

> (i) failed, in a systematic, widespread, and prolonged manner, to maintain effective controls to prevent diversion;
>
> (ii) failed, in a systematic, widespread, and prolonged manner, to design and operate effective systems to monitor suspicious orders;
>
> (iii) engaged in a systematic, widespread, and prolonged pattern of failing to identify and report thousands of specifically identifiable, suspicious orders for opioids;
>
> (iv) engaged in a systematic, widespread, and prolonged pattern of failing to prevent shipment and sale of thousands of specifically identifiable, suspicious orders for opioids.

He claims the methods he used to identify suspicious orders are appropriate, and some of which were utilized by the Defendants in one format or another for identifying groups of suspicious orders of opioids.

Rafalski claims he employed a similar methodology in formulating his opinions in this case that he utilized when serving as a DEA Divergent Investigator. His criminal investigations work gave him experience in record-keeping requirements at the pharmacy level with regard to distribution and dispensing.

He testified:

> Q. And when you conducted that Harvard investigation, did you employ the same methodology that we discussed earlier this morning?
>
> A Yes, ma'am.
>
> Q. And was it a reliable and generally accepted methodology?
>
> A Yes, ma'am. I think that any DEA investigator that would be tasked with this investigation would use generally the same methodology that I used.

Mr. Rafalski successfully investigated *Masters Pharmaceutical* in Ohio, which was a distributor allegedly shipping large quantities of opioids to Florida. He also investigated Mallinckrodt, an opioid manufacturer and defendant subject to a bankruptcy stay in this case.

Mr. Rafalski was asked to opine whether "each Defendant maintained adequate controls against diversion to identify and block suspicious orders." He performed an analysis with respect to Defendants Allergan, Teva, Janssen/Johnson & Johnson, Endo Pharmaceuticals, Mallinckrodt, AmerisourceBergen, McKesson, Cardinal Health, Walgreens, and CVS.

Describing how he performed that analysis, Mr. Rafalski testified as follows:

> A. ... I employed the same methodology or the same investigative techniques that I utilized when I was with the DEA. It was pretty much the standard type of investigation or the way that a standard investigation would be completed on these types of complex administrative matters.
>
> I first would request lots of documents. First, I'd like the transaction data for the time period that I was going to analyze. I was likely to require -- I'm sorry -- to request the suspicious order policies, the standard operating procedures, any of the procedures that had to do with the maintenance of effective controls that would be due diligence type of investigations, outside communications, emails, internal documents. And upon gaining all of those documents, I would analyze them.
>
> Q. Thank you. And when you did that, were you using the exact same approach or methodology that you employed when you were a diversion investigator for the DEA?
>
> A. Yes, it would be the same.

Plaintiffs suggest Rafalski's methodology for examining the Defendants' SOMs is the same he used when conducting investigations while employed by the DEA, and are reliable and well-founded, based on that experience. However, a formal *Frye* vetting misses

the mark of a Rafalski type witness offering opinions founded on experience (*see People v Oddone*, 22 N.Y.3d 369) (See footnote 5).

As concerns work experience, he testified that from 2010 to 2013, he conducted an administrative investigation of The Harvard Drug Group to identify unusual patterns of distribution of oxycodone to Florida pain clinics. His work included the review of company records and policies, as well as the DEA's ARCOS data and was ultimately successful. Also, from 2010 to 2013, Rafalski conducted an administrative investigation of *Masters Pharmaceutical*, reviewing company files regarding due diligence, including questionnaires, on-site investigation reports, and SOMS information. This investigation resulted in the DEA revoking the company's registration to manufacture and/or distribute controlled substances. *Id.; see Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

Rafalski devised methods to gauge the "effectiveness" of the Defendants/Petitioners' SOMs. Eventually his chosen model (Maximum Monthly, Trailing 6 month threshold) was deemed by him to be best suited for identifying suspicious orders. Plaintiffs point out that the method was endorsed by a Circuit Court (*Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d at 216-217:

> '[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.' Apparently tracking that regulatory language, the Computer Program held an order if: (a) that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months; (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months; or (c) the pharmacy's ordering pattern for a controlled medication deviated in some other notable way from its ordering pattern over the previous six months.

Masters suggests that, as a matter of common sense and logic, orders that deviate from a six-month trailing trend are "unusual" and not a "normal" occurrence.

As noted hereinbefore, and in considerations of the propriety of a *Frye* analysis concerning Rafalski, consider *People v Oddone*, 22 N.Y.3d 369 where the New York Court

of Appeals found:

> The flaw in defendant's reasoning is that Wilson did not claim to rely on any established scientific principle. He made clear that his testimony was based on his personal "experience"—meaning what he had observed, heard and read about particular cases. Such evidence is not barred by *Frye* (*see Johnson v State*, 933 So 2d 568, 570 [Fla App 2006] ["An expert opinion based on personal training and experience is not subject to a *Frye* analysis"]; *Commonwealth v Devlin, 365 Mass 149*, 155, 310 NE2d 353, 357 [1974] ["the Witness's opinion . . . was not the product of a 'scientific theory' but was, rather, the product of years of experience"])... It is true that an opinion based on experience alone is ordinarily less reliable than one based on generally accepted science. An expert may well overvalue his own experience, or even exaggerate or fabricate it. But these flaws can be exposed by cross-examination, and by the opinions of opposing experts.

The Court is not convinced that the excruciating cross examination of Mr. Rafalski precludes his testimony. The safeguards cited by the *Oddone* court are supported by the New York Pattern Jury Instructions.

Omissions suggested during cross examination of Rafalski are the basis of the Defendants claim that Rafalski admitted that he did not do even the most basic work to link his flagging methods to actual diversion.[6] Additionally, the Court will remain mindful of

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[6] • He did not review the due diligence files for his flagged orders to see if they appeared legitimate.
• He failed to review or evaluate any of the flagged orders themselves to determine whether they were actually suspicious.
• He failed to form an opinion on how much prescribing is legitimate, so that he could test his "likely to be diverted" claim.
• He ignored changes in medical practice that increased legitimate opioid prescribing.
• He failed to evaluate how many of his flagged orders actually went "to fill legitimate prescriptions based on legitimate needs of patients."
• He admitted that he did not know if any of the flagged orders were actually diverted.

the "cut and paste" process explored during cross examination. The same shall be fair game at trial.

At trial the finder of fact upon a thorough cross examination of Mr. Rafalski will have to determine if his models (created from on-the-job specialized experience) substantiate his opinions (if in fact his opinions are actually his own and not adopted from the complaint).

The Court adopts as its own and where relevant, concurs with the determination of Judge Polster, *MDL 2804 Doc. No. 2494 (8/20/2019).*

Therefore, it is

ORDERED ADJUDGED AND DECREED that Mr. Rafalski, subject to foundational requirements, separate and apart from the *Frye* analysis, may testify as an expert.

Following Mr. Rafalski's, Plaintiffs produced Dr. Craig McCann, an economist and data computation and analysis expert. McCann received a Ph.D. in economics from the University of California at Los Angeles in 1989. Throughout the 1990s, he taught graduate-level economics and finance courses at the University of South Carolina (1987 to 1992), Virginia Tech (1995 to 1997), Georgetown University (1996), and the University of Maryland (1995 to 1998). In addition, he served as an academic fellow for the U.S. Securities and Exchange Commission.

Since 1999, McCann's primary occupation has been to provide expert consultation and testimony in complex litigation involving securities class actions, investment management, labor, and valuation disputes.

It is apparent from Dr. McCann's credentials that he is removed from the pharmacy industry. However, that does not matter as his testimony essentially presents a digestion of data that he processed through the application of algorithms/metrics of Rafalski to arrive at findings. Those findings are offered to shed light on the issue of whether or not certain Defendants adequately investigated "flagged orders" and in the absence of investigation filled all subsequent orders relating to the same drug which were, as alleged, "suspicious."

The Food and Drug Enforcement Administration does not specifically endorse any specific suspicious order monitoring system (SOM). What is required is that registrants

construct an effective suspicious order methodology to target those orders in fulfilling their responsibility to detect and stop diversion. As noted in the comments accompanying the pattern jury instruction: the *Frye* test has traditionally asked whether the expert's methodologies and deductions have gained general acceptance as reliable in a scientific community... As an example, the Commentator notes a case where the Plaintiffs' expert's opinion on causation was inadmissible where other experts on whose work Plaintiffs' expert relied submitted affidavits directly controverting Plaintiffs' expert's theories and explaining how plaintiffs' expert had misrepresented their work; see *Matter of State of New York v lan 1.*, 127 A.D.3d 766 (2nd Dept. 2015).[7]

As further noted in the Commentaries:

> Where the scientific evidence proffered is not novel but there may be insufficient foundation for its application in the specific case, the court focuses not on the general reliability concerns addressed in the *Frye* test but on the specific reliability of the procedures followed to generate the evidence. . .In ruling upon whether a proper foundation has been established, the court should not make a determination on whether the evidence is true. (*emphasis added*)

Cross examination of Dr. McCann challenged both the foundational area of "specific reliability" and the accuracy of data Dr. McCann applied (ARCOS):

> Once the *Frye* reliability test and foundation requirements have been satisfied, it is for the jury to consider the weight of the evidence, including any possible infirmities in the collection and analysis of data. (See New York Pattern Jury Instruction)

As held by Judge Polster and as concurred by this Court, McCann applied Rafalski's five methods to DEA's Automation of Reports and Consolidation Orders System's ("ARCOS") data and Defendants' transactional data to identify suspicious transactions for specific Defendants. The Defendants point out that McCann has no experience in suspicious order monitoring. He has nothing to say about whether the methods he used are generally accepted, whether the orders he flagged were actually suspicious, or whether any of those orders were diverted or caused any harm in New York. This is entirely true.

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[7] New York State Pattern Jury Instruction 1:90.

However; it does not matter as McCann has not proffered as an expert in anything other than methodology (arithmetic) and his statistical analysis. Dr. McCann is a statistician with no history in the pharmaceutical industry. That is immaterial and irrelevant. He was engaged to use his skills, statistical and otherwise, applying the same to the models constructed by Mr. Rafalski. As to Dr. McCann and only Dr. McCann, the Court can find no basis to exclude his testimony provided good data (not garbage) went into his calculations, and Mr. Rafalski's means and methods comport with historical evidentiary mandates.

Therefore, it is

ORDERED ADJUDGED AND DECREED that Dr. McCann, subject to foundational requirements, separate and apart from the *Frye* analysis, may testify as an expert.

Next was the testimony of Dr. Anna Lembke – physician and addiction specialist. Dr. Lembke received an M.D. degree from the Stanford University School of Medicine in 1995, and also completed a partial residency in Pathology (1997), a full residency in Psychology (2000), and a Fellowship in Mood Disorders (2002). Since 2003, Lembke has served on the faculty at Stanford, where she has taught medical students, residents, and fellows on a variety of topics related to psychiatry, addiction, and pain. As a full-time faculty member, Lembke regularly treats patients who are addicted to opioids and other substances. For the past 15 years, her clinical practice "has included a significant proportion of patients taking prescription opioids for pain relief, for whom such drugs have resulted in misuse, dependence, and addiction." Lembke also sees patients at the Stanford Pain Clinic, where she provides expert consultation in pain and addiction.

Dr. Lembke offered testimony as to a methodology, its acceptance and reliability. The Defendants, as with all proffered experts, aggressively cross-examined Dr. Lembke.

Nonetheless, Dr. Lembke is qualified to offer the following opinions:

> l. Addiction is a chronic, relapsing and remitting disease with a behavioral component, characterized by neuroadaptive brain changes resulting from exposure to addictive drugs.... One of the biggest risk factors for addiction is simple access to addictive drugs. When supply of an addictive drug is increased, more people become addicted to and suffer the harms of that

drug. Prescription opioids are as addictive as heroin, and the Defendants' conduct in promoting increased supply and widespread access to prescription opioids has resulted in an epidemic of opioid addiction and overdose death.[8] (*emphasis added*)

2. Opioid prescribing began to increase in the 1980's and became prolific in the 1990's and the early part of the 21st century, representing a radical paradigm shift in the treatment of pain, and creating more access to prescription opioids across the United States.

3. The Pharmaceutical Opioid Industry contributed to the paradigm shift in opioid prescribing through promotional materials and its use and manipulation of key opinion leaders, continuing medical education courses, professional medical societies, the Federation of State Medical Boards, and the Joint Commission to convey misleading messages about the safety and efficacy of prescription opioids (see footnote 3).

4. No reliable scientific evidence shows that long-term opioid therapy is effective for chronic non-cancer pain.

5. Increased supply contributed to more individuals becoming addicted to opioids, including those who turned from prescription opioids to illicit sources of opioids such as heroin (The Gateway Effect).

6. Increased supply contributed to more individuals, including newborns, becoming dependent on opioids, increasing their risk for opioid-related morbidity and mortality (The Dependence Effect).

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[8] The Court sustains an objection concerning "marketing" - causation. Plaintiffs' proffer an opinion founded on "promotion." The Court affirms its findings but reserves to trial an opportunity to explore the difference, if any, between marketing and promotion. The Court will also consider whether such testimony concerning observations in marketing and/or promotion constitute circumstantial evidence as it is defined in the New York Pattern Jury Instructions 1:90.

7. Increased supply contributed to more diversion of prescription opioids, causing a dramatic increase in the widespread availability of opioids, including to individuals for whom opioids had not been prescribed (The Tsunami Effect).

8. The increased supply of prescription opioids through licit and illicit sources resulted in a prescription opioid epidemic in the United States. "Epidemic," defined as an outbreak of disease that spreads quickly and affects many individuals at the same time, is the appropriate term to describe the increase in opioid related morbidity and mortality beginning in the 1990's and continuing to the present day.

Therefore, it is

ORDERED ADJUDGED AND DECREED that Dr. Lembke, subject to foundational requirements, separate and apart from the *Frye* analysis, may testify as an expert.

The Court next heard Dr. Katherine Keyes. Katherine Keyes is an Associate Professor of Epidemiology at Columbia University, specializing in substance use and substance use disorders (epidemiology). She received her Ph. D. in Epidemiology from Columbia University and has published 225 peer-reviewed articles and book chapters. Her work appears in leading journals such as Pediatrics, JAMA Psychiatry, Lancet Psychiatry, American Journal of Epidemiology, and International Journal of Epidemiology, and is widely cited. Keyes has published two textbooks on epidemiological methods, both with Oxford University Press. She is an elected member of the executive board of the Society for Epidemiological Research and serves as Associate Editor of the Journal Drug and Alcohol Dependence. Keyes has received numerous professional awards honoring her research achievements, including early career achievement recognitions from the Research Society on Alcoholism, the American Psychopathological Association, the World Psychiatric Association Epidemiology and Public Health Section, and the NIH Office of Disease Prevention Early-Stage Investigator award. Of the 225 peer reviewed articles she has published, 19 peer-reviewed journal articles concentrated on opioid use and related harms, detailing trends over time in prescription opioid misuse, birth cohort trends in nonmedical opioid use and overdose, and risk factors for non-medical prescription opioid use, and consequences of use across developmental periods, including consequences related to overdose. She has particularly focused on "elucidating drivers of population-

level trends, including literature reviews, synthesis, and empirical analyses of urban-rural differences in nonmedical opioid use and overdose."

With regard to assessing opioid-related harm, Keyes describes the role of epidemiology to quantify: (1) the extent to which opioid use, and harms associated with opioid use, are changing over time; (2) the determinants of those changes; and (3) the individual-level risk factors for nonmedical opioid use and related harm. In assessing the causes of the opioid crises, Keyes applied a "risk factor" framework, where a given risk factor is considered to "be [a] cause[] of opioid use disorders, overdose, and related harm and if some cases would not have occurred in the absence of prescription opioid use." She notes: "[t]his framework does not preclude or ignore that addiction and related harms are multi-factorial in their etiology, but rather asks whether there are cases for which the outcome would not have occurred without the presence of prescription opioid use."

In reaching her opinions, Keyes reviewed various literature and studies to "assess the impact of opioid sales and distribution in the United States on opioid use disorders and addiction, overdose, diversion, transition to heroin, as well as the evidence-based recommendations for abatement." In so doing, Keyes relied on the methodology that she states is considered standard in the scientific process. First, she searched for peer-reviewed literature related to the areas of her review. Keyes states that, while peer-review is considered to be "the gold-standard," peer-review alone is not sufficient to establish the quality and validity of a scientific study. Thus, Keyes also performed her own review of the articles, based on her experience, "in order to discern whether they meet quality benchmarks;" In addition, Keyes included additional studies that she found relevant to each topic, as well as non-peer-reviewed "gray" literature. Keyes' Report includes two general categories of evidence: (1) studies that examined associations; and (2) studies that examined trends over time. Regarding studies that examined associations, Keyes considered the following levels of evidence: (1) randomized controlled trials, meta-analysis, and systematic reviews, which she designates as high levels of evidence; (2) studies that had prospective follow-up of participants, a well-described strategy for statistical control of confounders, and well-designed comparison groups, which she designates as the next level of evidence; and (3) well-designed studies of single populations without explicit comparison groups, which she designates as relevant evidence. Regarding studies that examined trends over time, Keyes considered three data sources to be the highest levels of evidence: (1) death records that are collected and harmonized by the national vital statistics surveillance system; (2) data sources with national reputation for transparency in reliability and validity that assess hospitalization and other clinical records; and (3) survey data that is routinely collected in the general population of households in

the United States over time.[9]

The Manufacturers and Distributors bring a Petition in connection with anticipated testimony of Dr. Katherine Keyes. Petitioners seek to preclude three (3) anticipated opinions to be offered through the Dr. Keyes. The three (3) areas are as follows: (l) Dr. Keyes claim that the Defendants are responsible for the harms caused by heroin and illegal fentanyl; (2) That the supply of prescription opioids was greater than medically necessary; and (3) Testimony suggesting the prevalence of "opioid use disorder," which she connects to the activities of the petitioning parties.

The Court is appreciative of the fact that the parties continually suggest referral to the decisions of Judge Polster. The Plaintiffs refer to document number 2518 filed August 26, 2019 in the MDL. Within that decision, the Court finds the following as well taken and adopts the same as its own:

> In the scope of the opioid epidemic, there is no meaningful distinction between (i) patients who started using prescription opioids as prescribed, but then began to overconsume because of dependence or addiction, and (ii) non-medical users who somehow overconsumed for other reasons. Likewise, some evidence suggests those who used prescription opioids without a prescription had the opportunity to do so because of the overabundance of these drugs in the medicine chests of their relatives or friends. Defendants' first contention, that the Experts' testimony must be excluded because none of the literature the Experts cite studied "medical users" of opioids, is, therefore, not well-taken. Defendants may explain to the jury why the distinction between these two populations in the literature is important; the distinction goes to the weight of the Experts' testimony, not its admissibility.

Furthermore, in the same decision, Judge Polster noted the following:

> But there is still reliable evidence from which one may reasonably infer that some heroin addiction results from opioid use. The strongest evidence is based on studies centered on

[9] Lemke and Keyes rely on their own publications, while Lemke further relies on her own first-hand experience from 15 years of clinical treatment of patients who suffered dependence and addiction after taking prescription opioids.

> non-medical users, but as the NASEM report stated, "[a] preponderance of evidence suggests that the major increase in prescription opioid use beginning in the late 1990s has served as a gateway to increased heroin use." NASEM Report at 215. The NASEM report further noted "the interrelated nature of the prescription and illicit opioid epidemics means that one cannot be addressed separately from the other." *Id.* at 248. The Muhuri, Lankenau, and Cicero studies provide a sturdy basis for the Experts' opinions; the Experts' reliance on observational studies simply reflects that these studies are the best evidence the discipline can point to where, as in the case of addiction to illicit and deadly substances, controlled clinical studies are not feasible. And Defendants' reference to the low proportion of prescription opioid users who go on to use heroin is a red herring, for the Experts do not opine that most people who use prescription opioids became addicted to heroin; rather, they opine that most people who are addicted to heroin first used prescription opioids.

After cross examination as well as the instructions set forth in the Pattern Jury Instructions for Trial courts in New York, all suggested flaws in Dr. Keyes opinions as set forth and recited by the Defendants can and will again be subject to cross-examination as to aid the jury in rendering a fair and honest verdict.

Therefore, it is

ORDERED ADJUDGED AND DECREED that Dr. Katherine Keyes, subject to foundational requirements, separate and apart from the *Frye* analysis, may testify as an expert.

After the testimony of Dr. Katherine Keyes, the Court heard the testimony of Dr. James Tomarken, a physician and former Suffolk County Health Commissioner.

The Plaintiffs seek to produce Dr. Tomarken as a "percipient"[10] witness. As noted by the Plaintiffs, Dr. Tomarken, unlike other expert witnesses who testified at the F*rye* hearings, is not a retained expert. The witness testified as to his medical and public health

[10] A percipient is a person having a good understanding of things.

training and essentially on the job-personal experience dealing with the opioid crisis during his 10 years as Suffolk County Health Commissioner. Plaintiffs' assert in their briefs that Dr. Tomarken " is prepared to offer testimony at trial about the nature of the opioid crisis on Long Island; the progress of that crisis over time; the three waves of the crisis; the nature of addiction as a disease; and the effects of the crisis on the public health. As further noted by Plaintiffs, much of the testimony Dr. Tomarken will offer will be facts rather than opinions. None of Defendants' arguments have any bearing on the admissibility of Dr. Tomarken's factual testimony.

In the event during the trial, Dr. Tomarken is called upon to offer an expert opinion the Court expressly acknowledges the rights reserved by all Defendants to object after which the Court will determine the admissibility of any such opinion.

Therefore, it is

ORDERED ADJUDGED AND DECREED that Dr. Tomarken, subject to foundational requirements, separate and apart from the *Frye* analysis, may testify as an expert.

The foregoing constitutes the decision and **ORDER** of the Court.

Dated: November 12, 2020

HON. JERRY GARGUILO, JSC